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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

MYLAN PHARMACEUTICALS INC.,

Plaintiff,

V.

CELGENE CORPORATION,

Defendant.

Civil Action No. 2:14 cv-02094-ES-MAH

Hon. Esther Salas, U.S.D.J.

Hon. Michael A. Hammer, U.S.M.J.

**ANSWER OF DEFENDANT CELGENE CORPORATION**

Defendant Celgene Corporation (“Celgene”) answers as follows the allegations in Plaintiff’s Complaint (“Complaint”).

The section headings from the Complaint are repeated below solely for ease of reference; by copying these section headings Celgene does not admit or attest to their accuracy.

## **I. Nature of the Action**

1. Celgene admits that Paragraph 1 of the Complaint correctly states Celgene's principal place of business. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in Paragraph 1 of the Complaint, and on that basis denies them.

2. Celgene admits that the cost of treatment with Thalomid® or Revlimid® varies by, among other things, the current unit price, the dose and duration of treatment, as well as any applicable insurance coverage or payment assistance. Celgene further admits that, subject to such factors, the cost per dose of treatment with Revlimid® is generally more expensive than the cost per dose of treatment with Thalomid®. Celgene states that the allegations in Paragraph 2 of the Complaint relating to sales revenues of Thalomid® and Revlimid® are vague as to time frame, that such sales revenue data are listed in Celgene's annual reports, and that those documents speak for themselves. Celgene denies the remaining allegations in Paragraph 2 of the Complaint.

3. Celgene admits the allegations in Paragraph 3 of the Complaint, with the clarification that Revlimid® is also indicated for multiple myeloma (in combination with dexamethasone) in patients who have received at least one prior therapy, and mantle cell lymphoma in patients whose disease has relapsed or progressed after two prior therapies (one of which included bortezomib).

4. Celgene admits the allegations in Paragraph 4 of the Complaint, with the clarification that the FDA approved Thalomid® and Revlimid® to be marketed only under strict risk management programs then known as Risk Minimization Action Plans ("RiskMAPs"), not

REMS. In 2008, pursuant to the Food & Drug Administration Amendments Act, FDA deemed Thalomid® and Revlimid® to each have a REMS.

5. Celgene admits that section 505-1(f)(8) of the Food Drug & Cosmetic Act states that “[n]o holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an application under section 355 (b)(2) or (j) of this title or to prevent application of such element under subsection (i)(1)(B) to a drug that is the subject of an abbreviated new drug application.” Celgene denies the remaining allegations in Paragraph 5 of the Complaint.

6. Celgene admits that the Hatch Waxman Act permits a generic drug manufacturer to seek FDA approval for a generic version of an approved reference listed drug (“RLD”) by filing an Abbreviated New Drug Application (“ANDA”). Celgene further admits that the Hatch Waxman Act requires an ANDA filer to demonstrate bioequivalence to the RLD. Celgene denies the remaining allegations in Paragraph 6.

7. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the third sentence of Paragraph 7 and on that basis denies it. Celgene denies the remaining allegations in Paragraph 7 of the Complaint.

8. Celgene admits that it settled litigation with Lannett relating to Thalomid® samples, that Dr. Reddy’s submitted a Citizen Petition to the FDA regarding Revlimid® samples, and that the Federal Trade Commission conducted an investigation relating to Celgene’s response to third parties seeking Thalomid® and Revlimid® for bioequivalence studies. Celgene denies the remaining allegations in Paragraph 8 of the Complaint.

9. Celgene denies the allegations in Paragraph 9 of the Complaint.

10. Celgene admits that the cost of treatment with Thalomid® or Revlimid® varies by, among other things, the current unit price, the dose and duration of treatment, as well as any applicable insurance coverage or payment assistance. Celgene states that the allegations in Paragraph 10 of the Complaint relating to sales revenues of Thalomid® and Revlimid® are vague as to time frame, that such sales revenue data are listed in Celgene's annual reports, and that those documents speak for themselves. Celgene denies the remaining allegations in Paragraph 10 of the Complaint.

11. Celgene admits that Mylan has filed an action seeking declaratory relief, treble damages, costs of suit, attorneys' fees, and injunctive relief. Celgene denies the remaining allegations in Paragraph 11 of the Complaint.

## **II. The Parties**

12. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 12 of the Complaint, and on that basis denies them.

13. Celgene admits the allegations in Paragraph 13 of the Complaint.

## **III. Jurisdiction and Venue**

14. Celgene admits that this purports to be a civil antitrust action brought under the named statutes, but denies that such an action is well founded.

15. Celgene admits that it markets and sells products in the United States and around the world. Celgene further admits that doctors prescribe Revlimid® and Thalomid® to patients and that in certain cases the drugs are ultimately purchased by wholesalers and patients. Celgene denies the remaining allegations in Paragraph 15 of the Complaint.

16. Celgene admits the allegations in Paragraph 16 of the Complaint.

17. Celgene admits the allegations in Paragraph 17 of the Complaint.

18. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 18 of the Complaint, and on that basis denies them.

19. Celgene admits that venue is proper in the District of New Jersey. Celgene otherwise denies the allegations in Paragraph 19 of the Complaint.

#### **IV. Statutory and Industry Background**

20. The allegations of Paragraph 20 set forth legal conclusions to which no response is required. To the extent any response is required, Celgene admits that FDA approval is required to market or sell a branded or generic drug product in the United States.

21. The allegations of Paragraph 21 set forth legal conclusions to which no response is required. To the extent any response is required, Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 21 of the Complaint, and on that basis denies them.

22. The allegations of Paragraph 22 set forth legal conclusions to which no response is required. To the extent any response is required, Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 22 of the Complaint, and on that basis denies them.

23. Celgene admits that the Bolar Amendment, 35 U.S.C. 271(e)(1), provides that it “shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information” for FDA approval. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 23 of the Complaint, and on that basis denies them.

24. The allegations of Paragraph 24 set forth legal conclusions to which no response is required. To the extent a response is required, Celgene admits that an ANDA filer is required

to demonstrate bioequivalence to the RLD. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 24 of the Complaint, and on that basis denies them.

25. Celgene admits that, depending on the circumstances, therapeutically-equivalent generics may receive an AB-rating. Celgene further admits that some states have generic substitution laws. Celgene otherwise denies the allegations in Paragraph 25 of the Complaint.

26. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first two sentences of Paragraph 26 of the Complaint, and on that basis denies them. Celgene denies the allegations in the third sentence of Paragraph 26.

27. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 27 of the Complaint, and on that basis denies them.

28. Celgene admits that some drugs are subject to FDA-mandated REMS programs due to safety concerns and thus may not be available through ordinary distribution channels. Celgene otherwise denies the allegations in Paragraph 28 of the Complaint.

29. Celgene admits that some drugs were subject to a RiskMAP in February 2007, but Celgene lacks knowledge or information sufficient to form a belief as to the exact number of such drugs or the content of their RiskMAPs. Celgene further admits that the FDA issued guidance for RiskMAPs in 2005. Celgene denies the remaining allegations in Paragraph 29 of the Complaint.

30. The allegations of Paragraph 30 set forth legal conclusions to which no response is required. Celgene admits that in 2007 FDA was given the authority to require REMS programs, which programs may include the various elements described in the last sentence of Paragraph 30. Celgene otherwise denies the allegations in Paragraph 30 of the Complaint.

31. Celgene denies the allegations in the first sentence of Paragraph 31. Celgene admits that § 505-1(f)(8) of the FDC Act states that “[n]o holder of an approved covered application shall use any element to assure safe use required by [FDA] under [FDC Act § 505-1(f)] to block or delay approval of an application under Section 505(b)(2) or (j) or to prevent application of such element under [FDC Act § 505-1(i)(1)(B)] to a drug that is the subject of an [ANDA].” Celgene lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 31 of the Complaint, and on that basis denies them.

32. To the extent that the allegations in Paragraph 32 of the Complaint are applied to Celgene, Celgene denies them. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 32 of the Complaint, and on that basis denies them.

33. Celgene denies the allegations in Paragraph 33 of the Complaint.

#### **V. Benefits of Generic Competition**

34. Celgene admits that generic drugs are sometimes sold at a lower price than the branded RLD. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 34 of the Complaint, and on that basis denies them.

35. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 35 of the Complaint, and on that basis denies them.

#### **VI. Relevant Market and Market Power**

##### ***Thalidomide Market***

36. Celgene denies the allegations in Paragraph 36 of the Complaint.

37. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 37, and on that basis denies them. Celgene denies the remaining allegations in Paragraph 37 of the Complaint.

38. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 38 of the Complaint, and on that basis denies them.

39. Celgene denies the allegations in Paragraph 39 of the Complaint.

40. Celgene denies the allegations in Paragraph 40 of the Complaint.

41. Celgene denies the allegations in Paragraph 41 of the Complaint.

42. Celgene denies the allegations in Paragraph 42 of the Complaint.

43. Celgene denies the allegations in Paragraph 43 of the Complaint.

44. Celgene admits that it is the only company with FDA approval to sell and market thalidomide under the brand name Thalomid®. Celgene denies the remaining allegations of Paragraph 44 of the Complaint.

45. Celgene denies the allegations in Paragraph 45 of the Complaint.

***Lenalidomide Market***

46. Celgene denies the allegations in Paragraph 46 of the Complaint.

47. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 47, and on that basis denies them. Celgene denies the remaining allegations in Paragraph 47 of the Complaint.

48. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 48 of the Complaint, and on that basis denies them.

49. Celgene denies the allegations in Paragraph 49 of the Complaint.

50. Celgene denies the allegations in Paragraph 50 of the Complaint.

51. Celgene denies the allegations in Paragraph 51 of the Complaint.



52. Celgene denies the allegations in Paragraph 52 of the Complaint.

53. Celgene denies the allegations in Paragraph 53 of the Complaint.

54. Celgene admits that it is the only company with FDA approval to sell and market lenalidomide under the brand name Revlimid®. Celgene denies the remaining allegations of Paragraph 54 of the Complaint.

55. Celgene denies the allegations in Paragraph 55 of the Complaint.

## **VII. Background on Thalidomide and Lenalidomide**

56. Celgene admits the allegations in the first sentence of Paragraph 56 of the Complaint. Celgene further admits that it is engaged in discovery, development, and commercialization of therapies designed to treat cancer and other severe, immune, or inflammatory conditions. Celgene denies the remaining allegations in Paragraph 56 of the Complaint.

57. Celgene admits the first two sentences of Paragraph 57 of the Complaint, with the clarifications that Celgene also markets Otezla® (apremilast) and Celgene does not market azacitidine. Celgene admits that its 2013 Annual Report shows combined sales of Thalomid® and Revlimid® reaching in the billions of dollars in each of 2011, 2012, and 2013, and that these combined sales constituted between 71% and 75% of Celgene's total net product sales during those years.

### ***Thalidomide***

58. Celgene admits the allegations in Paragraph 58 of the Complaint.

59. Celgene admits the allegations in Paragraph 59 of the Complaint with the clarification that, in addition to manufacturing Thalomid®, Celgene also developed Thalomid®.

60. Celgene admits that the FDA conditioned approval of Thalomid® on a proprietary, comprehensive, education and risk-management distribution program with the objective of preventing fetal exposure to the drug. Celgene otherwise denies the allegations in Paragraph 60 of the Complaint.

61. Celgene admits the allegations in Paragraph 61 of the Complaint.

62. Celgene admits the allegations in Paragraph 62 of the Complaint.

63. Celgene admits that Thalomid® is only available through a proprietary risk management distribution program approved by the FDA and tailored specifically to provide for the safe and appropriate distribution and use of Thalomid®, and that this program was once called the System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.®) but is now called Thalomid REMS®. Celgene admits that the second sentence of Paragraph 63 of the Complaint lists some requirements of S.T.E.P.S.® (now Thalomid REMS®), but denies that Paragraph 63 contains an adequate or complete description of S.T.E.P.S.® (now Thalomid REMS®). Celgene otherwise denies the allegations in Paragraph 63 of the Complaint.

64. Celgene admits that the FDA-approved REMS program for Thalomid® allows for only registered patients to receive Thalomid®. Celgene otherwise denies the allegations in Paragraph 64 of the Complaint.

65. Celgene admits that it has provided Thalomid® to research organizations, including Johns Hopkins University School of Medicine, for the purpose of conducting clinical studies and that patients enrolled in such studies are included in Celgene's REMS program. Celgene denies the remaining allegations of Paragraph 65 of the Complaint.

#### *Lenalidomide*

66. Celgene admits the allegations in Paragraph 66 of the Complaint.

67. Celgene admits the allegations in Paragraph 67 of the Complaint.

68. Celgene admits that the sales figures listed in Paragraph 68 of the Complaint are accurate. Celgene otherwise denies the allegations in Paragraph 68 of the Complaint.

69. Celgene admits that Revlimid® is only available through a proprietary risk management distribution program approved by the FDA and tailored specifically to provide for the safe and appropriate distribution and use of Revlimid®, and that this program was once called RevAssist® but is now called Revlimid REMS®. Celgene admits that the third sentence of Paragraph 69 of the Complaint lists some requirements of RevAssist® (now Revlimid REMS®), but denies that Paragraph 69 contains an adequate or complete description of RevAssist® (now Revlimid REMS®). Celgene otherwise denies the allegations in Paragraph 69 of the Complaint.

70. Celgene admits that the FDA-approved REMS program for Revlimid® allows for only registered patients to receive Revlimid®. Celgene otherwise denies the allegations in Paragraph 70 of the Complaint.

71. Celgene admits that it has provided Revlimid® to research organizations, including those organizations listed in Paragraph 71, for the purpose of conducting clinical studies and that patients enrolled in such studies are included in Celgene's REMS program. Celgene denies the remaining allegations of Paragraph 71 of the Complaint.

#### **VIII. Allegations regarding "Defendant's Unlawful Conduct"**

72. Celgene denies the allegations in Paragraph 72 of the Complaint.

73. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 73 of the Complaint, and on that basis denies them.

74. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 74 of the Complaint, and on that basis denies them.

75. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 75 of the Complaint, and on that basis denies them. Celgene admits that it received letters from Dinsmore & Shohl LLP on October 5, 2004 and May 3, 2005, requesting to purchase Thalomid® capsules.

76. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 76 of the Complaint, and on that basis denies them.

77. Celgene admits that Mylan contacted Celgene on or about September 2, 2005 and that Paragraph 77 accurately quotes portions of that correspondence. Celgene otherwise denies the allegations in Paragraph 77.

78. Celgene admits that it sent a letter to Mylan on October 20, 2005 and that Paragraph 78 of the Complaint accurately quotes portions of that letter. Celgene otherwise denies the allegations in Paragraph 78.

79. Celgene admits that it sent a letter to Mylan on December 19, 2005, and that Paragraph 79 accurately quotes portions of that letter. Celgene denies the remaining allegations in Paragraph 79.

80. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 80 of the Complaint, and on that basis denies them.

81. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 81 of the Complaint, and on that basis denies them.

82. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 82 of the Complaint, and on that basis denies them.

83. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 83 of the Complaint, and on that basis denies them.

84. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 84 of the Complaint, and on that basis denies them.

85. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 85 of the Complaint, and on that basis denies them.

86. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 86 of the Complaint, and on that basis denies them.

87. Celgene admits the allegations in Paragraph 87 of the Complaint.

88. Celgene admits the allegations in the first sentence of Paragraph 88 of the Complaint. Celgene admits that Mylan again requested Thalomid® capsules and stated that it was “prepared to pay full value.” Celgene otherwise denies the allegations in Paragraph 88.

89. Celgene admits that Mylan contacted Celgene on or about December 4, 2007 and that Paragraph 89 accurately quotes portions of that correspondence. Celgene otherwise denies the allegations in Paragraph 89.

90. Celgene admits that its attorneys sent a letter to Mylan on January 8, 2008 (the “January 8, 2008 Letter”). Celgene denies the remaining allegations in Paragraph 90.

91. Celgene admits that Paragraph 91 of the Complaint accurately quotes portions of the January 8, 2008 Letter. Celgene denies the remaining allegations in Paragraph 91.

92. Celgene admits that there was a discrepancy regarding the number of capsules requested by Mylan (2,600) and the number of capsules the FDA’s letter stated it would permit Celgene to provide to Mylan (500). Celgene denies the remaining allegations in Paragraph 92.

93. Celgene admits that the first sentence of Paragraph 93 of the Complaint accurately quotes portions of the January 8, 2008 Letter. Celgene denies the remaining allegations in Paragraph 93.

94. Celgene admits that the January 8, 2008 Letter discussed significant business and liability concerns associated with Celgene's distribution of Thalomid® to Mylan. Celgene denies the remaining allegations in Paragraph 94.

95. Celgene admits that the January 8, 2008 Letter requested certain information from Mylan. Celgene denies the remaining allegations in Paragraph 95.

96. Celgene admits the allegations in Paragraph 96 of the Complaint.

97. Celgene admits that the January 8, 2008 Letter requested Mylan's "history of compliance with FDA regulatory requirements for the previous five years, including warning letters and FDA Form 483's[.]" Celgene denies the remaining allegations in Paragraph 97.

98. Celgene admits that the last sentence of Paragraph 98 of the Complaint accurately quotes from the January 8, 2008 Letter. Celgene denies the remaining allegations in Paragraph 98.

99. Celgene admits that the January 8, 2008 Letter asked whether Mylan's product liability insurance covered thalidomide. Celgene denies the remaining allegations in Paragraph 99.

100. Celgene admits that the second sentence of Paragraph 100 of the Complaint accurately quotes from the January 8, 2008 Letter. Celgene denies the remaining allegations in Paragraph 100.

101. Celgene denies the allegations in Paragraph 101 of the Complaint.

102. Celgene admits that Paragraph 102 of the Complaint accurately quotes from the letter from Mylan dated February 25, 2008 (the “February 25, 2008 Letter”). Celgene denies the remaining allegations in Paragraph 102.

103. Celgene admits that Paragraph 103 of the Complaint accurately quotes from the February 25, 2008 Letter. Celgene also admits that the letter enclosed a confidentiality agreement. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of the last sentence of Paragraph 103 of the Complaint, and on that basis denies them. Celgene denies the remaining allegations in Paragraph 103.

104. Celgene admits that its attorneys proposed edits to Mylan’s confidentiality agreement on April 18, 2008 and that Mylan accepted Celgene’s edits. Celgene denies the remaining allegations in Paragraph 104.

105. Celgene admits that its attorneys proposed edits to Mylan’s confidentiality agreement in early June 2008 and that Mylan accepted Celgene’s edits. Celgene denies the remaining allegations in Paragraph 105.

106. Celgene admits that it executed the confidentiality agreement on June 24, 2008. Celgene denies the remaining allegations in Paragraph 106.

107. Celgene admits that its attorneys received a letter from Mylan dated June 27, 2008, purporting to respond to the January 8, 2008 Letter. Celgene denies the remaining allegations in Paragraph 107.

108. Celgene admits the allegations in Paragraph 108 of the Complaint.

109. Celgene denies the allegations in Paragraph 109 of the Complaint.

110. Celgene admits that Paragraph 110 of the Complaint accurately quotes from Mylan's letter to Sidley Austin dated June 27, 2008. Celgene denies the remaining allegations in Paragraph 110.

111. Celgene admits that Mylan contacted Celgene on or about July 25, 2008. Celgene otherwise denies the allegations in Paragraph 111.

112. Celgene admits the allegations in Paragraph 112 of the Complaint.

113. Celgene admits that its attorneys provided a draft indemnification agreement to Mylan on August 15, 2008, and further admits that Celgene's attorneys received a letter from Mylan on October 10, 2008. Celgene denies the remaining allegations in Paragraph 113.

114. Celgene admits that Mylan was unwilling to agree to the indemnification terms Celgene requested. Celgene denies the remaining allegations in Paragraph 114 of the Complaint.

115. Celgene admits that Mylan's letter of October 10, 2008 addressed indemnification. Celgene otherwise denies the allegations in Paragraph 115.

116. Celgene admits that the first sentence of Paragraph 116 accurately quotes from Mylan's letter dated October 10, 2008, that Mylan enclosed a revised draft indemnification agreement, and that Mylan's letter stated that Mylan believed it had fully responded to Celgene's requests and that the parties had reached the four year anniversary date of Mylan's initial request to Celgene. Celgene denies the remaining allegations in Paragraph 116.

117. Celgene denies the allegations in Paragraph 117 of the Complaint.

118. Celgene admits that its attorneys sent a letter to Mylan on October 31, 2008 (the "October 31, 2008 Letter") and that the final four words in Paragraph 118 of the Complaint quote accurately from that letter. Celgene denies the remaining allegations in Paragraph 118.



119. Celgene admits that the October 31, 2008 Letter contained the statement that Celgene has no legal obligation to provide Thalomid® to Mylan. Celgene denies the remaining allegations in Paragraph 119 of the Complaint.

120. Celgene admits that its attorneys received a letter from Mylan on April 20, 2009, attaching certificates of insurance from Mylan and its contract research organization. Celgene denies the remaining allegations in Paragraph 120 of the Complaint.

121. Celgene denies the allegations in Paragraph 121 of the Complaint.

122. Celgene admits that its attorneys sent a letter to Mylan on June 24, 2009 (the “June 24, 2009 Letter”) and that the final sentence of Paragraph 122 of the Complaint accurately quotes from that letter. Celgene denies the remaining allegations in Paragraph 122.

123. Celgene admits that the quoted portion of the first sentence of Paragraph 123 is an accurate quotation from the June 24, 2009 Letter. Celgene denies the remaining allegations in Paragraph 123.

124. Celgene admits that the June 24, 2009 Letter identified the outstanding issues remaining before Celgene would agree to sell Thalomid® to Mylan and urged Mylan to respond “as quickly as possible.” Celgene denies the remaining allegations in Paragraph 124 of the Complaint.

125. Celgene admits that the June 24, 2009 Letter requested that Mylan and Mylan’s CRO change their insurance coverage for thalidomide to occurrence-based policies. Celgene further admits that the letter rejected some of Mylan’s revisions to the indemnification agreement. Celgene denies the remaining allegations of Paragraph 125 of the Complaint.

126. Celgene admits that the June 24, 2009 Letter requested evidence of FDA approval of Mylan's protocol. Celgene denies the remaining allegations of Paragraph 126 of the Complaint.

127. Celgene admits the allegations of the second sentence of Paragraph 127 of the Complaint. Celgene denies the remaining allegations of Paragraph 127 of the Complaint.

128. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 128 of the Complaint regarding Mylan's decision to engage further with Celgene, and on that basis denies them. Celgene denies the remaining allegations of Paragraph 128 of the Complaint.

129. Celgene denies the allegations in Paragraph 129 of the Complaint.

130. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 130 of the Complaint relating to Mylan's consideration of filing an ANDA for lenalidomide and its attempts to obtain samples through wholesale distributors, and on that basis denies them. Celgene denies the remaining allegations of Paragraph 130 of the Complaint.

131. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 131 of the Complaint, and on that basis denies them.

132. Celgene admits that samples of Revlimid® are needed to conduct bioequivalence testing. Celgene lacks knowledge or information sufficient to form a belief as to the availability of Revlimid® through "normal wholesale distribution channels" and on that basis denies the remaining allegations in the first sentence of Paragraph 132. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the third sentence of Paragraph 132 of the Complaint regarding Mylan's conclusions about obtaining Revlimid® from

Celgene, and on that basis denies them. Celgene denies the remaining allegations of Paragraph 132 of the Complaint.

133. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 133 of the Complaint, and on that basis denies them.

134. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 134 of the Complaint, and on that basis denies them.

135. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 135 of the Complaint, and on that basis denies them.

136. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 136 of the Complaint, and on that basis denies them.

137. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 137 of the Complaint, and on that basis denies them.

138. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 138 of the Complaint, and on that basis denies them.

139. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 139 of the Complaint, and on that basis denies them.

140. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 140 of the Complaint, and on that basis denies them.

141. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 141 of the Complaint, and on that basis denies them.

142. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 142 of the Complaint, and on that basis denies them.

143. Celgene admits that it received a letter from Mylan on May 1, 2013 requesting to purchase 1,100 capsules each of the 15 mg and 25 mg strengths, and 200 capsules each of the 2.5 mg, 5 mg, and 10 mg strengths of Revlimid® for purposes of bioequivalence testing. Celgene denies the remaining allegations in Paragraph 143.

144. Celgene admits that it sent a letter to Mylan on May 14, 2013 stating its intent to sell Revlimid® to Mylan for bioequivalence testing upon Celgene's satisfactory review of certain documents and information and upon execution of a Supply Agreement. Celgene denies the remaining allegations in Paragraph 144.

145. Celgene admits that certain requests in its May 14, 2013 letter to Mylan are similar to requests made in Celgene's January 8, 2008 letter to Mylan. Celgene denies the remaining allegations in Paragraph 145.

146. Celgene admits that the bullet point list in Paragraph 146 contains general (though incomplete) descriptions of certain requests Celgene made in its May 14, 2013 letter to Mylan. Celgene denies the remaining allegations in Paragraph 146.

147. Celgene admits the allegations in Paragraph 147 of the Complaint.

148. Celgene denies the allegations in Paragraph 148 of the Complaint.

149. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 149 of the Complaint, and on that basis denies them.

150. Celgene lacks knowledge or information sufficient to form a belief as to whether the March 11, 2014 letter from Mylan to Celgene followed FDA's "final endorsement of [Mylan's] safety protocols," and on that basis denies the allegation. Celgene admits the remaining allegations in Paragraph 150 of the Complaint.

151. Celgene admits that Mylan's letter dated March 11, 2014 attached an indemnification agreement. Celgene further admits that the quoted portions of Paragraph 151 of the Complaint are accurate quotations from Mylan's letter. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 151 of the Complaint as to what terms were "agreeable to Mylan," and on that basis denies them. Celgene denies the remaining allegations in Paragraph 151.

152. Celgene admits that it sent a letter to Mylan on March 20, 2014, in part reiterating the requests it made to Mylan in Celgene's letter dated May 14, 2013. Celgene denies the remaining allegations in Paragraph 152.

153. Celgene admits that its letter to Mylan dated March 20, 2014 requested written confirmation that the FDA will allow Celgene to sell the requested amount of Revlimid® to Mylan. Celgene further admits that the quoted portions of Paragraph 153 of the Complaint are accurate. Celgene denies the remaining allegations in Paragraph 153.

154. Celgene admits that the bullet point list in Paragraph 154 contains general (though incomplete) descriptions of certain requests Celgene made in its March 20, 2014 letter to Mylan. Celgene denies the remaining allegations in Paragraph 154.

155. Celgene admits that the quoted portions of Paragraph 155 of the Complaint are accurate quotations. Celgene denies the remaining allegations in Paragraph 155.

156. Celgene admits that its letter to Mylan dated March 20, 2014 did not enclose a signed indemnification agreement. Celgene further admits that the quoted portions of Paragraph 156 of the Complaint are accurate quotations from Celgene's letter. Celgene denies the remaining allegations in Paragraph 156.

157. Celgene denies the allegations in Paragraph 157 of the Complaint.

**VIII. Allegations regarding the “Anticompetitive Effects of Defendant’s Conduct”**

158. Celgene denies the allegations in Paragraph 158 of the Complaint.

159. Celgene admits that FDA approval is required before a company may market a generic thalidomide or lenalidomide product. To the extent that the second sentence of Paragraph 159 of the Complaint refers to the time involved and costs incurred by generic companies, Celgene lacks knowledge or information sufficient to form a belief as to the truth of these allegations, and on that basis denies them. Celgene denies the remaining allegations in Paragraph 159 of the Complaint.

160. Celgene admits that it provides Thalomid® and Revlimid® to certain parties pursuant to Celgene’s REMS programs. Celgene further admits that it prohibits those parties from reselling Thalomid® and Revlimid® to unauthorized purchasers. Celgene denies the remaining allegations in Paragraph 160 of the Complaint.

161. Celgene admits that it has provided Thalomid® and Revlimid® to research organizations for use in clinical studies and that patients enrolled in such studies are included in Celgene’s REMS program. Celgene denies the remaining allegations in Paragraph 161 of the Complaint.

162. Celgene admits that it has provided Thalomid® and Revlimid® to research organizations, including those organizations listed in Paragraph 162, for the purpose of conducting clinical studies and that patients enrolled in such studies are included in Celgene’s REMS program. Celgene denies the remaining allegations in Paragraph 162 of the Complaint.

163. Celgene denies the allegations in Paragraph 163 of the Complaint.

164. Celgene denies the allegations in Paragraph 164 of the Complaint.

165. Celgene denies the allegations in Paragraph 165 of the Complaint.

166. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 166 of the Complaint, and on that basis denies them.

167. Celgene denies the allegations in Paragraph 167 of the Complaint.

168. Celgene denies the allegations in Paragraph 168 of the Complaint.

169. Celgene denies the allegations in Paragraph 169 of the Complaint.

170. Celgene denies the allegations in Paragraph 170 of the Complaint.

171. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 171 of the Complaint, and on that basis denies them.

172. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 172 of the Complaint, and on that basis denies them.

173. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 173 of the Complaint, and on that basis denies them.

174. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 174 of the Complaint regarding what steps Mylan has taken toward attempting to develop its generic thalidomide and lenalidomide capsule products, and on that basis denies them. Celgene denies the remaining allegations in Paragraph 174 of the Complaint.

175. Celgene lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 175 of the Complaint regarding Mylan's expenditures to develop generic thalidomide and lenalidomide, and on that basis denies them.

176. Celgene hereby incorporates its responses to each preceding Paragraph as if fully set forth herein.

177. Celgene denies the allegations in Paragraph 177 of the Complaint.

178. Celgene denies the allegations in Paragraph 178 of the Complaint.

179. Celgene denies the allegations in Paragraph 179 of the Complaint.

180. Celgene denies the allegations in Paragraph 180 of the Complaint.

181. Celgene denies the allegations in Paragraph 181 of the Complaint.

182. Celgene denies the allegations in Paragraph 182 of the Complaint.

183. Celgene denies the allegations in Paragraph 183 of the Complaint.

184. Celgene denies the allegations in Paragraph 184 of the Complaint.

185. Celgene denies the allegations in Paragraph 185 of the Complaint.

186. Celgene denies the allegations in Paragraph 186 of the Complaint.

**FIRST COUNT: Alleged Violation of Sherman Act Section 2 – Thalomid® – Monopolization, Attempted Monopolization and Conspiracy to Monopolize**

187. Celgene hereby incorporates its responses to each preceding Paragraph as if fully set forth herein.

188. Celgene denies the allegations in Paragraph 188 of the Complaint.

189. Celgene denies the allegations in Paragraph 189 of the Complaint.

190. Celgene admits that the Complaint purports to state a claim arising under the Sherman Act and Clayton Act as stated in Paragraph 190 of the Complaint.

191. Celgene denies the allegations in Paragraph 191 of the Complaint.

192. Celgene denies the allegations in Paragraph 192 of the Complaint.

193. Celgene denies the allegations in Paragraph 193 of the Complaint.

194. Celgene denies the allegations in Paragraph 194 of the Complaint.

195. Celgene denies the allegations in Paragraph 195 of the Complaint.

196. Celgene denies the allegations in Paragraph 196 of the Complaint.

197. Celgene denies the allegations in Paragraph 197 of the Complaint.



198. Celgene denies the allegations in Paragraph 198 of the Complaint.

199. Celgene denies the allegations in Paragraph 199 of the Complaint.

200. Celgene denies the allegations in Paragraph 200 of the Complaint.

201. Celgene denies the allegations in Paragraph 201 of the Complaint.

202. Celgene denies the allegations in Paragraph 202 of the Complaint.

203. Celgene denies the allegations in Paragraph 203 of the Complaint.

204. Celgene denies the allegations in Paragraph 204 of the Complaint.

**SECOND COUNT: Alleged Violation of Sherman Act Section 2 – Revlimid® – Monopolization, Attempted Monopolization and Conspiracy to Monopolize**

205. Celgene hereby incorporates its responses to each preceding Paragraph as if fully set forth herein.

206. Celgene denies the allegations in Paragraph 206 of the Complaint.

207. Celgene denies the allegations in Paragraph 207 of the Complaint.

208. Celgene admits that the Complaint purports to state a claim arising under the Sherman Act and Clayton Act as stated in Paragraph 208 of the Complaint.

209. Celgene denies the allegations in Paragraph 209 of the Complaint.

210. Celgene denies the allegations in Paragraph 210 of the Complaint.

211. Celgene denies the allegations in Paragraph 211 of the Complaint.

212. Celgene denies the allegations in Paragraph 212 of the Complaint.

213. Celgene denies the allegations in Paragraph 213 of the Complaint.

214. Celgene denies the allegations in Paragraph 214 of the Complaint.

215. Celgene denies the allegations in Paragraph 215 of the Complaint.

216. Celgene denies the allegations in Paragraph 216 of the Complaint.

217. Celgene denies the allegations in Paragraph 217 of the Complaint.

218. Celgene denies the allegations in Paragraph 218 of the Complaint.

219. Celgene denies the allegations in Paragraph 219 of the Complaint.

220. Celgene denies the allegations in Paragraph 220 of the Complaint.

221. Celgene denies the allegations in Paragraph 221 of the Complaint.

222. Celgene denies the allegations in Paragraph 222 of the Complaint.

223. Celgene denies the allegations in Paragraph 223 of the Complaint.

**THIRD COUNT: Alleged Violation of Sherman Act Section 2 – Thalomid® –  
Denial of an Essential Facility or Resource Necessary to Compete**

224. Celgene hereby incorporates its responses to each preceding Paragraph as if fully set forth herein.

225. Celgene admits that the Complaint purports to state a claim arising under the Sherman Act and Clayton Act as stated in Paragraph 225 of the Complaint.

226. Celgene denies the allegations in Paragraph 226 of the Complaint.

227. The allegations of Paragraph 227 set forth legal conclusions to which no response is required.

228. Celgene denies the allegations in Paragraph 228 of the Complaint.

229. Celgene denies the allegations in Paragraph 229 of the Complaint.

230. Celgene denies the allegations in Paragraph 230 of the Complaint.

231. Celgene denies the allegations in Paragraph 231 of the Complaint.

232. Celgene denies the allegations in Paragraph 232 of the Complaint.

233. Celgene denies the allegations in Paragraph 233 of the Complaint.

234. Celgene denies the allegations in Paragraph 234 of the Complaint.

235. Celgene denies the allegations in Paragraph 235 of the Complaint.

236. Celgene denies the allegations in Paragraph 236 of the Complaint.

237. Celgene denies the allegations in Paragraph 237 of the Complaint.

238. Celgene denies the allegations in Paragraph 238 of the Complaint.

239. Celgene denies the allegations in Paragraph 239 of the Complaint.

240. Celgene denies the allegations in Paragraph 240 of the Complaint.

**FOURTH COUNT: Alleged Violation of Sherman Act Section 2 – Revlimid® –  
Denial of an Essential Facility or Resource Necessary to Compete**

241. Celgene hereby incorporates its responses to each preceding Paragraph as if fully set forth herein.

242. Celgene admits that the Complaint purports to state a claim arising under the Sherman Act and Clayton Act as stated in Paragraph 242 of the Complaint.

243. Celgene denies the allegations in Paragraph 243 of the Complaint.

244. The allegations of Paragraph 244 set forth legal conclusions to which no response is required.

245. Celgene denies the allegations in Paragraph 245 of the Complaint.

246. Celgene denies the allegations in Paragraph 246 of the Complaint.

247. Celgene denies the allegations in Paragraph 247 of the Complaint.

248. Celgene denies the allegations in Paragraph 248 of the Complaint.

249. Celgene denies the allegations in Paragraph 249 of the Complaint.

250. Celgene denies the allegations in Paragraph 250 of the Complaint.

251. Celgene denies the allegations in Paragraph 251 of the Complaint.

252. Celgene denies the allegations in Paragraph 252 of the Complaint.

253. Celgene denies the allegations in Paragraph 253 of the Complaint.

254. Celgene denies the allegations in Paragraph 254 of the Complaint.

255. Celgene denies the allegations in Paragraph 255 of the Complaint.

256. Celgene denies the allegations in Paragraph 256 of the Complaint.

257. Celgene denies the allegations in Paragraph 257 of the Complaint.

**FIFTH COUNT: Alleged Violation of Sherman Act Section 1 – Thalomid® –  
Contract, Combination or Conspiracy in Restraint of Trade**

258-270. Plaintiff's claims identified in Paragraphs 258-270 of the Complaint have been dismissed pursuant to the Court's Order of December 23, 2014 (Dkt. No. 54), and thus Celgene is not required respond.

**SIXTH COUNT: Alleged Violation of Sherman Act Section 1 – Revlimid® –  
Contract, Combination or Conspiracy in Restraint of Trade**

271-283. Plaintiff's claims identified in Paragraphs 271-283 of the Complaint have been dismissed pursuant to the Court's Order of December 23, 2014 (Dkt. No. 54), and thus Celgene is not required to respond.

**SEVENTH COUNT: Alleged Violation of Sherman Act Section 1 – Thalomid®  
and Revlimid® – Contract, Combination or Conspiracy in Restraint of Trade**

284-298. Plaintiff's claims identified in Paragraphs 284-298 of the Complaint have been dismissed pursuant to the Court's Order of December 23, 2014 (Dkt. No. 54), and thus Celgene is not required to respond.

**EIGHTH COUNT: Alleged Violation of The New Jersey Antitrust Act,  
Sections 56:9-3 and 56:9-4 – Thalomid®**

299. Celgene hereby incorporates its responses to each preceding Paragraph as if fully set forth herein.

300. Celgene admits that the Complaint purports to state a claim arising under the New Jersey Antitrust Act as stated in Paragraph 300 of the Complaint.

301. Celgene denies the allegations in Paragraph 301 of the Complaint.

302. Celgene denies the allegations in Paragraph 302 of the Complaint.

303. Celgene denies the allegations in Paragraph 303 of the Complaint.

304. Celgene denies the allegations in Paragraph 304 of the Complaint.

305-307. Plaintiff's claims identified in Paragraphs 305-307 of the Complaint have been dismissed pursuant to the Court's Order of December 23, 2014 (Dkt. No. 54), and thus Celgene is not required to respond.

308. Celgene denies the allegations in Paragraph 308 of the Complaint.

309. Celgene denies the allegations in Paragraph 309 of the Complaint.

310. Celgene denies the allegations in Paragraph 310 of the Complaint.

311. Celgene denies the allegations in Paragraph 311 of the Complaint.

312. Plaintiff's claims relating to a purported violation of Section 56:9-3 of the New Jersey Antitrust Act have been dismissed pursuant to the Court's Order of December 23, 2014 (Dkt. No. 54), and thus Celgene is not required to respond. Celgene denies the remaining allegations in Paragraph 312 of the Complaint.

**NINTH COUNT: Alleged Violation of The New Jersey Antitrust Act,  
Sections 56:9-3 and 56:9-4 – Revlimid®**

313. Celgene hereby incorporates its responses to each preceding Paragraph as if fully set forth herein.

314. Celgene admits that the Complaint purports to state a claim arising under the New Jersey Antitrust Act as stated in Paragraph 314 of the Complaint.

315. Celgene denies the allegations in Paragraph 315 of the Complaint.

316. Celgene denies the allegations in Paragraph 316 of the Complaint.

317. Celgene denies the allegations in Paragraph 317 of the Complaint.

318. Celgene denies the allegations in Paragraph 318 of the Complaint.

319-321. Plaintiff's claims identified in Paragraphs 319-321 of the Complaint have been dismissed pursuant to the Court's Order of December 23, 2014 (Dkt. No. 54), and thus Celgene is not required to respond.

322. Celgene denies the allegations in Paragraph 322 of the Complaint.

323. Celgene denies the allegations in Paragraph 323 of the Complaint.

324. Celgene denies the allegations in Paragraph 324 of the Complaint.

325. Celgene denies the allegations in Paragraph 325 of the Complaint.

326. Plaintiff's claims relating to a purported violation of Section 56:9-3 of the New Jersey Antitrust Act have been dismissed pursuant to the Court's Order of December 23, 2014 (Dkt. No. 54), and thus Celgene is not required to respond. Celgene denies the remaining allegations in Paragraph 326 of the Complaint.

**TENTH COUNT: Alleged Violation of The New Jersey Antitrust Act,  
Sections 56:9-3 and 56:9-4 – Thalomid® and Revlimid®**

327. Celgene hereby incorporates its responses to each preceding Paragraph as if fully set forth herein.

328. Celgene admits that the Complaint purports to state a claim arising under the New Jersey Antitrust Act as stated in Paragraph 328 of the Complaint.

329. Celgene denies the allegations in Paragraph 329 of the Complaint.

330. Celgene denies the allegations in Paragraph 330 of the Complaint.

331. Celgene denies the allegations in Paragraph 331 of the Complaint.

332. Celgene denies the allegations in Paragraph 332 of the Complaint.

333-335. Plaintiff's claims identified in Paragraphs 333-335 of the Complaint have been dismissed pursuant to the Court's Order of December 23, 2014 (Dkt. No. 54), and thus Celgene is not required to respond.

336. Celgene denies the allegations in Paragraph 336 of the Complaint.

337. Celgene denies the allegations in Paragraph 337 of the Complaint.

338. Celgene denies the allegations in Paragraph 338 of the Complaint.

339. Celgene denies the allegations in Paragraph 339 of the Complaint.

340. Plaintiff's claims relating to a purported violation of Section 56:9-3 of the New Jersey Antitrust Act have been dismissed pursuant to the Court's Order of December 23, 2014 (Dkt. No. 54), and thus Celgene is not required to respond. Celgene denies the remaining allegations in Paragraph 340 of the Complaint.

**ELEVENTH COUNT: Alleged Violation of Common Law of the  
State of New Jersey – Thalomid® – Unfair Competition**

341. Celgene hereby incorporates its responses to each preceding Paragraph as if fully set forth herein.

342. Celgene denies the allegations in Paragraph 342 of the Complaint.

343. Celgene denies the allegations in Paragraph 343 of the Complaint.

**TWELFTH COUNT: Alleged Violation of Common Law of the  
State of New Jersey – Revlimid® – Unfair Competition**

344. Celgene hereby incorporates its responses to each preceding Paragraph as if fully set forth herein.

345. Celgene denies the allegations in Paragraph 345 of the Complaint.

346. Celgene denies the allegations in Paragraph 346 of the Complaint.

**THIRTEENTH COUNT: Alleged Violation of Common Law of the  
State of New Jersey – Thalomid® and Revlimid® – Unfair Competition**

347. Celgene hereby incorporates its responses to each preceding Paragraph as if fully set forth herein.

348. Celgene denies the allegations in Paragraph 348 of the Complaint.

349. Celgene denies the allegations in Paragraph 349 of the Complaint.

**FOURTEENTH COUNT: Alleged Violation of Common Law of the  
State of New Jersey – Thalomid® – Tortious Interference  
with an Economic Advantage**

350. Celgene hereby incorporates its responses to each preceding Paragraph as if fully set forth herein.

351. Celgene admits the allegations in Paragraph 351 of the Complaint.

352. Celgene denies the allegations in Paragraph 352 of the Complaint.

353. Celgene denies the allegations in Paragraph 353 of the Complaint.

354. Celgene denies the allegations in Paragraph 354 of the Complaint.

355. Celgene denies the allegations in Paragraph 355 of the Complaint.

356. Celgene denies the allegations in Paragraph 356 of the Complaint.

357. Celgene denies the allegations in Paragraph 357 of the Complaint.

**FIFTEENTH COUNT: Alleged Violation of Common Law of the  
State of New Jersey – Revlimid® – Tortious Interference  
with an Economic Advantage**

358. Celgene hereby incorporates its responses to each preceding Paragraph as if fully set forth herein.

359. Celgene admits the allegations in Paragraph 359 of the Complaint.

360. Celgene denies the allegations in Paragraph 360 of the Complaint.

361. Celgene denies the allegations in Paragraph 361 of the Complaint.

362. Celgene admits the allegations in the first sentence of Paragraph 362 of the Complaint. Celgene denies the remaining allegations in Paragraph 362 of the Complaint.

363. Celgene denies the allegations in Paragraph 363 of the Complaint.

364. Celgene denies the allegations in Paragraph 364 of the Complaint.

365. Celgene denies the allegations in Paragraph 365 of the Complaint.



**SIXTEENTH COUNT: Alleged Violation of Common Law of the  
State of New Jersey – Thalomid® and Revlimid® – Tortious Interference  
with an Economic Advantage**

366. Celgene hereby incorporates its responses to each preceding Paragraph as if fully set forth herein.

367. Celgene admits the allegations in Paragraph 367 of the Complaint.

368. Celgene denies the allegations in Paragraph 368 of the Complaint.

369. Celgene denies the allegations in Paragraph 369 of the Complaint.

370. Celgene denies the allegations in Paragraph 370 of the Complaint.

371. Celgene admits the allegations in the first sentence of Paragraph 371 of the Complaint. Celgene denies the remaining allegations in Paragraph 371 of the Complaint.

372. Celgene denies the allegations in Paragraph 372 of the Complaint.

373. Celgene denies the allegations in Paragraph 373 of the Complaint.

374. Celgene denies the allegations in Paragraph 374 of the Complaint.

375. Celgene denies the allegations in Paragraph 375 of the Complaint.

**SEVENTEENTH COUNT: Alleged Violation of Declaratory Judgment  
Pursuant to 28 U.S.C. §§ 2201-2202**

376. Celgene hereby incorporates its responses to each preceding Paragraph as if fully set forth herein.

377. Celgene admits that the Complaint purports to state a claim for declaratory judgment under 28 U.S.C. §§ 2201-2201.

378. Celgene denies the allegations in Paragraph 378 of the Complaint.

379. Celgene denies the allegations in Paragraph 379 of the Complaint.

380. Celgene denies the allegations in Paragraph 380 of the Complaint.

To the extent a response is required to the Prayer for Relief and Demand for Jury Trial, Celgene denies the allegations contained therein and states that Plaintiff is not entitled to any of the remedies set out in the Complaint.

Celgene denies each and every allegation of the Complaint not specifically admitted.

### **AFFIRMATIVE AND OTHER DEFENSES**

Without assuming any burden that it would not otherwise bear, Celgene asserts the following defenses to the Complaint. Further, Celgene reserves all affirmative defenses under Fed. R. Civ. P. 8(c) and any other defenses, at law or in equity, that may now exist or in the future be available based on discovery and further factual investigation in this case.

#### First Defense

Plaintiff's claims are barred in whole or in part for failure to state a claim upon which relief can be granted.

#### Second Defense

Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations, and the doctrines of laches, waiver, and estoppel. Celgene did not commit any act, such as fraudulent concealment, that could render these defenses inapplicable.

#### Third Defense

Any and all of Celgene's actions alleged by Plaintiff were lawful, justified, procompetitive, and carried out in furtherance of Celgene's legitimate business interests.

#### Fourth Defense

To the extent Plaintiff's claims are based in whole or in part on Celgene's petitioning activity, Plaintiff's claims are barred by the immunity conferred on Celgene by the First Amendment and the *Noerr* doctrine.

Fifth Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff has not suffered any actual injury or damage as a result of any conduct alleged as a basis of this lawsuit because, among other things, Thalomid® and Revlimid® are covered by numerous unexpired patents that would preclude Plaintiff from commercializing a generic version of either drug.

Sixth Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff has not suffered injury proximately caused by any conduct of Celgene and/or has not suffered, and will not suffer, injury of the type that the relevant statutes were designed to prevent.

Seventh Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff's alleged damages, if any, are too speculative and uncertain.

Eighth Defense

Plaintiff's claims are barred, in whole or in part, because the acts or omissions of Celgene did not substantially lessen competition through the exercise of market power in any properly defined market.

Ninth Defense

Plaintiff's claims are barred, in whole or in part, because Celgene's alleged conduct was unilateral, reasonable, and based on independent, legitimate safety and business justifications.

Tenth Defense

Plaintiff is not entitled to any form of preliminary or permanent injunctive relief.

Eleventh Defense

Plaintiff's New Jersey common law claims for tortious interference fail because

Celgene's conduct was not tortious, was without malice, had legitimate justification, and such conduct did not cause damage to Mylan.

**DEMAND FOR A STATEMENT OF DAMAGES PURSUANT TO L. CIV. R. 8.1**

Celgene demands that Plaintiff serve a written statement of the amount of damages claimed in this action within fourteen (14) days pursuant to L. Civ. R. 8.1.

**PRAYER FOR RELIEF**

WHEREFORE, Celgene prays for relief as follows:

- (a) That the Complaint against Celgene be dismissed in its entirety, with prejudice, and that the plaintiff take nothing.
- (b) That Celgene be awarded its attorneys' fees and costs and expenses of the suit; and
- (c) That the Court award such other and further relief as the Court deems just and proper.

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Dated: January 20, 2015

**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

I certify that the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

/s/ Daniel R. Guadalupe

Dated: January 20, 2015

**CERTIFICATION OF SERVICE**

I certify that this Answer was filed and served within the time permitted by the Federal Rules of Civil Procedure and the Local Civil Rules, as extended by Order of the Court filed on January 13, 2015 (Dkt. No. 61). Filing and service were effected by electronically filing this Answer with the Clerk for the United States District Court for the District of New Jersey by using the Court's CM/ECF system, which will automatically send email notification of such filing to all attorneys of record and will likewise be available electronically to any attorneys of record who subsequently appear in this matter. A courtesy copy of this Answer also was sent by PDF email to:

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*Attorneys for Plaintiff Mylan Pharmaceuticals Inc.*

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

/s/ Daniel R. Guadalupe

Dated: January 20, 2015